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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,838	11/29/2004	Shmuel A. Ben-Sasson	24348-501 NATL	6386
<div>30623 7590 07/23/2007</div> <div>MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111</div>				
EXAMINER				
GUDIBANDE, SATYANARAYAN R				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
07/23/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,838	Applicant(s) BEN-SASSON ET AL.	
	Examiner Satyanarayana R. Gudibande	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-20, 26, 27, 31-50, 53-56, 63 and 68-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 15-20, 26, 27, 31-50, 53-56, 63, 68-125 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Previous election restriction dated 10/18/05 has been vacated in lieu of the instant election restriction.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 15, 16, 17-20, 26, 27, 31-38, 53, drawn to a penetrating module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide consisting of at least one amino acid sequence selected from the group consisting of: a) SEQ ID NOS: 1-15; b) SEQ ID NOS: 25-29 and; c) at least 12 contiguous amino acids of any of the peptides in a) or b), wherein said penetrating peptide is capable of translocating the effector across a biological barrier, wherein, when the effector is a polypeptide, the penetrating module is encoded by a chimeric gene sequence.

Group II, claim(s) 39-47, drawn to a method of a method of producing the penetrating module of said method comprising coupling said effector to said penetrating peptide.

Group III, claim(s) 48-50, drawn to method of producing the penetrating module, wherein the coupling of said effector to said penetrating peptide is achieved by a non-covalent bond..

Group IV, claim(s) 54 and 55, drawn to a method of treating or preventing a disease or pathological condition.

Group V, claim(s) 56, 79 and 80, drawn to a method for producing the penetrating module of claim 1 comprising a) transfecting a production cell with a vector comprising a nucleic acid molecule of a fusion protein encoding said penetrating peptide and an effector operably linked to an expression control sequence; b) culturing said production cell under conditions that permit production of a fusion protein consisting of the penetrating peptide and an effector peptide; and c) isolating said fusion protein.

Art Unit: 1654

Group VI, claim(s) 63, drawn to the penetrating module of claim 1, wherein said penetrating peptide is derived from a human neurokinin receptor, and is characterized by the ability to penetrate biological barriers in vivo.

Group VII, claim(s) 68-75, drawn to the penetrating module of claim 1, further comprising a molecular vessel selected from the group consisting of a soluble receptor, a minireceptor, and a binding protein, wherein said penetrating peptide is coupled or fused to the molecular vessel, which encloses the effector..

Group VIII, claim(s) 76, drawn to a method for producing the penetrating module of claim 1 comprising using solid-phase peptide synthesis.

Group IX, claim(s) 77 and 78, drawn to a penetrating module wherein the bioactive peptide comprises a chemical modification.

Group X, claim(s) 81, drawn to a penetrating module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide consisting of at least one amino acid sequence selected from the group consisting of: a) SEQ ID NOS: 1-15; and b) SEQ ID NOS: 24-29, wherein said penetrating peptide is capable of translocating the effector across a biological barrier, wherein, when the effector is a polypeptide, the penetrating module is encoded by a chimeric gene sequence.

Group XI, claim(s) 82, drawn to a penetrating module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide comprising at least one amino acid sequence selected from the group consisting of: a) SEQ ID NOS: 25-29 and; b) at least 12 contiguous amino acids of any of the peptides in a), wherein said penetrating peptide is capable of translocating across a biological barrier.

Group XII, claim(s) 83, drawn to a penetrating module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide comprising at least one amino acid sequence selected from the group consisting of SEQ ID NOS: 25-29, wherein said penetrating peptide is capable of translocating across a biological barrier.

Group XIII, claim(s) 84-87, drawn to the penetrating module of claim 1, wherein the effector is covalently bound to the penetrating peptide.

Group XIV, claim(s) 88-91, drawn to the penetrating module of claim 1, wherein the effector is ionically bound to the penetrating peptide.

Group XV, claim(s) 92-96 and 97-107, drawn to a penetrating module consisting of a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide consisting of at least one amino acid sequence selected from the group consisting of: a) SEQ ID NO: 24 and; b) at least 12 contiguous amino acids of any of SEQ ID NO:24, wherein said penetrating peptide is capable of translocating the effector across a biological barrier,

Art Unit: 1654

wherein, when the effector is a polypeptide, the penetrating module is encoded by a chimeric gene sequence.

Group XVI, claim(s) 108-115, drawn to a pharmaceutical composition comprising a therapeutically or prophylactically effective amount of the penetrating module according to claim 108, and a pharmaceutically acceptable carrier.

Group XVII, claim(s) 116-117, drawn to the penetrating module of claim 93, wherein the bioactive peptide further comprises a chemical modification.

Group XVIII, claim(s) 118-121, drawn to the penetrating module of claim 92, wherein the effector is covalently bound to the penetrating peptide.

Group XIX, claim(s) 122-125, drawn to the penetrating module of claim 92, wherein the effector is ionically bound to the penetrating peptide.

According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XIX do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a penetrating module comprising a penetrating peptide and an effector, which is shown by the amino acid sequence of penetrating peptide SEQ ID No. 1, (EP 1 136 557 A1 of Schilfgaard, et al.). The reference discloses a penetrating peptide sequence (SEQ ID No. 4, page 19) that comprises the SEQ ID No. 1 of the instant application that crosses epithelial cell membranes. The two N-terminal amino acids and the amino acid residues 26-205 of the disclosed sequence could be an effector molecule because the effector molecule can be any bioactive molecule. Therefore, the special technical feature of group I invention is known and hence is not a contribution over the prior art and hence the inventions I-XIX lack unity of invention.

Art Unit: 1654

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

Claims **1, 82 and 92** are generic to the following disclosed patentably distinct species: **peptides**. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of peptide with a corresponding SEQ ID NO., associated with the elected species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species **peptides**. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of peptide with a corresponding SEQ ID NO., associated with the elected species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claims 45, 81, 83** are generic.

Claims **1, 15-18, 39, 68, 81-96, 108 and 118-125** are generic to the following disclosed patentably distinct species: an **effector molecule**. The species are independent or distinct because the disclosed effectors belong to several general classes of compounds and as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of an effector. If applicant chooses to elect a peptide, applicant is required provide the corresponding SEQ ID NO., associated with the elected species, if applicant chooses to elect an organic molecule as an effector, applicant is required to provide the structural features of the molecule, etc., for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.**

Claim **32 and 100** are generic to the following disclosed patentably distinct species: **non-ionic detergent, ionic detergent, protease inhibitor and a reducing agent**. The species are independent or

Art Unit: 1654

distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of required reagent, if for example, applicants chooses ionic detergent and a protease inhibitor, applicants are required to provide SEQ ID Nos., and structural features of the molecules** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claim 42 is generic to the following disclosed patentably distinct species: **bridging reagent**. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of bridging agent with structural features of the reagent or SEQ ID NO., associated with the bridging agent if the bridging agent is a peptide or polynucleotide** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claim 53 is generic to the following disclosed patentably distinct species: **disease or a pathological condition**. The species are independent or distinct because they affect different patient population and exhibit distinct etiology as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of a disease or a pathological condition** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claim 68 is generic to the following disclosed patentably distinct species: **of soluble receptor, a mini receptor and a binding protein**. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species of soluble receptor, a mini receptor and a binding protein with either structural features of the elected species or with the sequence information associated with the elected species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 79 and 116 are generic to the following disclosed patentably distinct species: **chemical modification of bioactive peptide and fusion protein respectively**. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed chemical modification with associated structural features of the final modified product** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1654

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Art Unit: 1654

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

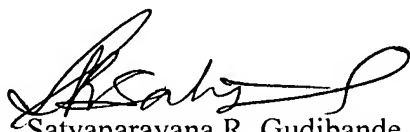
Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

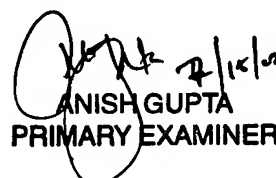
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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